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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,488	03/17/2000	Najla Guthrie	52953.8	3790

25295 7590 05/20/2003

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BELTSVILLE, MD 20705-5131

EXAMINER
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OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

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DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/528,488

Applicant(s)

GUTHRIE ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Response to Arguments

The following is in response to the amendment filed 3/4/03:

An action on the merits of claims 13 - 22 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claim Rejections - 35 U.S.C. § 103**

Claims 13-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Guthrie et al., U.S. 2001/0055627.

Claims 13- 15 are drawn to a method of reducing the level of apolipoprotein B production comprising administering an effective amount of a polymethoxyflavone.

Claims 16-22 are drawn to polymethoxyflavone compositions suitable for reducing the level of apolipoprotein B.

Guthrie teaches that flavonoids, including polymethoxyflavones such as nobiletin and tangeretin (p.2, paragraph 0008) inhibit LDL cholesterol and apolipoprotein B (apo-B) synthesis, and are thus effective for reducing atherosclerosis, hypercholesterolemia and lowering the risk of cardiovascular disease (p.3, paragraph 27). Guthrie further teaches that apolipoprotein B is the principal protein of LDL and that the binding of apo-B to LDL receptors results in internalization and degradation of LDL , promoting clearance of LDL from plasma and regulating intracellular cholesterol handling. Although Guthrie does not teach all of the polymethoxyflavones claimed, Guthrie does teach flavones/flavonoids broadly for the use of reducing apo-B levels, as well as those specific polymethoxyflavones such as nobiletin and tangeretin. As such, applicant's use of polymethoxyflavones which are members of the broad class recited in Guthrie for the same purpose of reducing apo-B levels is encompassed by the teachings of Guthrie.

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Applicant has set forth compositions wherein known polymethoxyflavones are combined for reducing the level of substances which contribute to cardiovascular diseases or disorders. The combination of two compounds known to achieve the same effect in a composition is seen as obvious, unless there is some unexpected result. The prior art has clearly set forth the use of specifically claimed polymethoxyflavones, and the class of flavones/flavonoids broadly as agents effective in reducing apo-B. Thus combinations of these agents into a composition would be obvious.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use a polymethoxyflavones in a composition for reducing the level of apolipoprotein B.

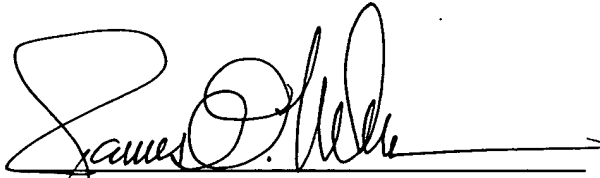
A person of ordinary skill in the art would have been motivated to use polymethoxyflavones in a composition for reducing the level of apolipoprotein B given that the prior art has set forth that flavones, specifically polymethoxyflavones act as agents which reduce the level of apolipoprotein B and LDL cholesterol, which consequently reduces the incidence of cardiovascular diseases, atherosclerosis, or hypercholesterolemia.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Howard V. Owens  
Patent Examiner  
Art Unit 1623

A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.